



\*\*\*\* Recall Notification\*\*\*\*

24<sup>th</sup> November 2010

Dear Cochlear Implant Clinician,

Our mission at Advanced Bionics is to improve the lives of the hearing impaired, and the safety and well-being of our recipients is our first priority. Because we are committed to ensuring that our products are as safe as possible, we are voluntarily informing you that we have become aware of a very rare issue with the HiRes 90K cochlear implant. The issue can result in pain, very loud sounds or sudden shocking sensations in the implanted ear while the implant is powered. Our investigation shows that of the more than 28,000 implanted HiRes 90K devices, only two (0.007%) explanted devices have been confirmed to have this issue. Both recipients were re-implanted with HiRes 90K devices and their clinicians report that they are progressing well.

We have conducted an extensive evaluation of this issue using an independent scientific research organization. Their current analysis suggests that, if present, the issue will first occur within 90 days of device use. If this issue has not occurred within the first 90 days of device use, the recipient is unlikely to be affected. However, if the device is not used regularly, the onset of symptoms may be delayed after initial activation.

As a precautionary measure, we are informing the Competent Authority that we are instituting a voluntary product recall. We request that all scheduled surgeries be postponed and that all unused HiRes 90K cochlear implants be returned to Advanced Bionics. We are implementing changes to ensure that no future devices will have this issue. During this time, the manufacturing and distribution of all HiRes 90K devices will be temporarily suspended.

If a recipient under your care reports extreme pain while the implant is powered, advise them to remove the external equipment immediately. This issue can be intermittent. In the unlikely event that this symptom occurs, continued device use may lead to damage of the auditory nerve.

It is important to note that it is not unusual for cochlear implant recipients to experience overly loud sounds. Most of these cases can be resolved with standard troubleshooting, such as the replacement of external equipment. The vast majority of these cases are not signs of the issue described above and do not require explanation of the device.

If a recipient under your care reports or demonstrates an extreme pain reaction, schedule an appointment to complete the attached troubleshooting steps. If your evaluation of their condition suggests that the implant exhibits this problem, device replacement is advised.

If our records showed that you have any unregistered implants in your possession, a list of serial numbers was provided for devices that must be returned to Advanced Bionics.



We sincerely regret any concern this notification may cause. Advanced Bionics assures you that we will correct this issue and continue to improve our product reliability.

If you have questions, require assistance with troubleshooting, or possess unused product for return, please contact your local Advanced Bionics representative.

In order to assure the effectiveness of this communication, please complete the enclosed acknowledgment form and return it to us at your earliest convenience by using one of the following options:

E-mail: [regulatory@abionics.fr](mailto:regulatory@abionics.fr)

Fax: +33 389 655005

Mail: Advanced Bionics SARL  
76, rue de Battenheim  
F-68170 Rixheim  
France

Sincerely,

Michael E. Sundler  
Senior Vice President



## Troubleshooting Steps for Identified HiRes 90K Recipients:

1. Identified recipient is reporting/showing signs of extreme pain with their typical program:
  - a. Exchange all external equipment.
  - b. Create a program with all M's set to 0.
  - c. Try the 'zero' M program.
  - d. If the recipient hears nothing/does not demonstrate an adverse reaction, they do not have the issue. Discontinue use of the 'zero' M program.
  - e. If they experience extreme pain or demonstrate an extreme adverse reaction with this program, discontinue use of the sound processor. It is likely that they have an implant with this issue.
  - f. Contact your AB Clinical Specialist or Technical Service Europe.
  
2. Identified recipient has previously experienced extreme pain but is not currently experiencing/showing signs of extreme pain with their typical program:
  - a. Exchange all external equipment.
  - b. Create a program with all M's set to 0.
  - c. Try the 'zero' M program. Confirm that no sound is heard by recipient. In the case of a non-reporter, no adverse reaction should be observed.
  - d. Download the program to a slot on the recipient's sound processor for take-home use. Instruct the recipient/caregiver to try this program only if extreme pain is experienced related to use of their typical program.
  - e. After 90 days, if they have not experienced the symptom with their typical program, they are no longer at risk. The 'zero' M program can be removed from their sound processor during their next scheduled clinic visit.
  - f. If the recipient experiences/demonstrates extreme pain within 90 days of device use and it also occurs with the 'zero' M program, it is likely that the recipient has an implant with this issue.
  - g. Contact your AB Clinical Specialist.
  
3. Identified recipient has never experienced/shown signs of extreme pain with their typical program:
  - a. Create a program with all M's set to 0.
  - b. Try the "zero" M program. Confirm that no sound is heard by the recipient. In the case of a non-reporter, no adverse reaction should be observed.
  - c. Download the program to a slot on the recipient's sound processor for take-home use. Instruct the recipient/caregiver to try it only if the symptom appears related to use of their typical program.
  - d. After 90 days of implant use, if they have not experienced extreme pain with their typical program, they are no longer at risk. The 'zero' M program can be removed from the recipient's sound processor during their next scheduled clinic visit.
  - e. If the recipient experiences/demonstrates extreme pain within 90 days of device use and it also occurs with the 'zero' M program, it is likely that the recipient has an implant with this issue.
  - f. Contact your AB Clinical Specialist.



Technical Service Europe

phone: +33 (389) 634026

[eurosupport@abionics.fr](mailto:eurosupport@abionics.fr)



**HiRes 90K<sup>®</sup> Implant Notification  
Acknowledgement Form**

November 2010

Dear Clinician,

Please sign this form and fax it to +33 389 655005. If you have any technical questions, please call your local AB representative.

I have read and understood the Recall Notification of November 24, 2009, regarding the HiRes 90K Implant.

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed Name